

## SAMPLES COMPLIANCE COMMITTEE MINUTES OF 5/24/93

The Samples Compliance Committee (SCC) meet on Monday, May 24, 1993. The following people were in attendance:

Alan MacKenzie  
Dean Sundberg  
Jeff Peterson  
Kevin Lowe  
Bob Berman  
Lori Hernandez

### Policy/Procedure Review

- A. Sample Audit Action Plan  
The Action Plan resulting from the Audit of the TAP Sample Process was presented by Kevin Lowe. A few changes were suggested. Kevin stated that the plan would be finalized and routed for signatures this week. It is planned to forward the plan to Abbott the week of 5/31. (final copy attached)
- B. Revised Policy/Procedures Manual  
A revised samples procedures manual was presented containing the changes as required by the sample audit. These procedures will also be circulated the week of 5/31 for signatures.
- C. Physician Assistants in Washington State  
The laws relating to supplying samples to Physician's Assistants in the state of Washington was reviewed and the distribution of samples to this group was approved. A letter will be sent to Epsilon revising their instruction appropriately.
- D. District Compliance  
The performance of TAP in balancing the samples distributed was reviewed. During the first quarter of 1993, the percent of products in balance for the nation as a whole has varied between 60% and 70%. For April the percent was 71%. This is much lower than we had hoped for. It was suggested that a letter be sent to any Representative after they show any variance for a third consecutive month. such a letter will be drafted. It was also suggested a letter for the W. Hall be sent emphasizing the importance of this area and that sampling be a topic for the next District Managers meeting.

TAP00063274



E. DM Inventory

As of 5/24, the response level of the first Inventory Audit by the District Manager was 75%. The DMs still owing a response have been notified by Voice-Com.

## Representative Review

1. Multiple Adjustments - The list of Sales Representatives that has used three or more adjustments in the last six months was reviewed.

All individuals were found to be in compliance with Federal regulations. Concern was expressed that it is taking a long time for some people to get into balance once they are out.

2. High per Doctor Sampling Average - The list of Sales Representatives with a high samples per Physician average when compared to their District Average was reviewed.

All individuals on the list were found to be in compliance with Federal regulations.

It was suggested that the screening criteria be added to the bottom of this report for reference.

3. Special Situations - The list of special situations not covered by the two categories above but who do warrant concern was reviewed.

All individuals on the list were found to be in compliance with Federal regulations.

Concern was again expressed as to the length of time that some people are out of balance. The criticism has been heard that once you are out of balance you stay that way. The system does carry a problem forward but only until that specific item is corrected. A card that is return to a Representative will continue to cause that Representative to be out of balance until the card is fixed and returned to Epsilon. If the representative takes 6 months to return the item they will be out of balance for 6 months

TAP00063275

ACTION PLAN

TAP Pharmaceuticals

Ref. Document: Compliance Assurance Audit

Report Date: 5/28/93

<u>Observation Number</u>	<u>Description</u>	<u>Responsible Individual</u>	<u>Target Date</u>
1.	<p>Operating procedures which describe the TAP Drug Sampling program were reviewed and the following noted:</p> <ul style="list-style-type: none"><li>a. Procedures were not issued within a control system that includes QA review and approval.</li><li>b. Procedures were out-of-date in that aspects of the program which changed on September 1, 1992 were not detailed. For example, there are no provisions describing Lupron sample distribution by representatives no are there instructions for completion of the returned goods authorization form regarding the storage statement.</li></ul>	K. Lowe	Complete
	<p>Action Plan:</p> <ul style="list-style-type: none"><li>a. TAP QA Management will review and approve SOP's governing TAP's Drug Sampling Program.</li><li>b. TAP's Sampling standard operating procedures have been updated and approved.</li></ul>	B. Berman, K. Lowe	Complete

TAP00063276

ACTION PLAN

TAP Pharmaceuticals

Ref. Document: Compliance Assurance Audit

Report Date: 5/28/93

<u>Observation Number</u>	<u>Description</u>	<u>Responsible Individual</u>	<u>Target Date</u>
2.	There was no assurance that sales representatives store drug samples under satisfactory conditions in that there were no procedural definitions of what constitutes satisfactory conditions or other storage requirements including temperature and security. Additionally, there was no requirement that either the sales representative or the District Manager attest to the adequacy of storage conditions. It should be noted that Ogen tablets require storage at temperatures less than 77 F.	B. Berman	Complete
3.	No procedures have been developed to assure that violations of the Act are communicated to the Secretary of HHS by either TAP or Abbott management. For example, the Division documented a theft of drug samples from a salesman's car in June 1992. The Secretary of HHS has not been notified as required by the PDMA.	B. Berman, K. Lowe	Complete

ACTION PLAN

TAP Pharmaceuticals

Ref. Document: Compliance Assurance Audit

Report Date: 5/28/93

<u>Observation Number</u>	<u>Description</u>	<u>Responsible Individual</u>	<u>Target Date</u>
4.	<p>The Division employs a third-party contractor to process its drug sampling documentation. The contractor, Epsilon Incorporated, employs a computerized system to track the shipment, disbursement and return of sales representatives' samples. Documentation is lacking for several important aspects of validation and a documented rationale has not been developed which would exempt the system from the requirements of validation. For example, there was no certification of the system by either TAP or Epsilon, formal change control and re-validation criteria have not been developed, data retention policies have not been defined and software development standards have not been established.</p>	B. Berman, K. Lowe	Complete

Action Plan:

TAP management has determined the system meets validation exclusion criteria due to the following rationale: The system does not affect manufacturing product conformance to specifications nor lot traceability. Pharmaceutical sample distribution computer systems are not directly governed by GMP regulations. End-users (TAP in-house personnel & Sales Representative employees) perform a manual verification that the data output is complete and accurate. Additionally, Epsilon's sample computer system is currently utilized by approximately ten other major pharmaceutical companies for their commercial sampling programs.

TAP00063278

ACTION PLAN

TAP Pharmaceuticals

Ref. Document: Compliance Assurance Audit

Report Date: 5/28/93

<u>Observation Number</u>	<u>Description</u>	<u>Responsible Individual</u>	<u>Target Date</u>
5.	<p>Procedures used by Epsilon which describe the processing of TAP's drug sampling cards were reviewed and the following noted:</p> <p>a. The procedures were not signed/approved by TAP or Epsilon personnel nor were the procedures dated. It should be noted that the procedures were identified as Revision 2 and contained blank spaces for both parties' approval.</p> <p>b. The procedures were out-of-date in that several practices which recently became effective were not described. For example, reportedly nurse practitioners in Washington state were now being sampled even though the current procedures limit sampling to MDs or DOs.</p>	B. Berman, A. MacKenzie	Complete

Action Plan: TAP sales administration management will review and approve all Epsilon vendor procedures and policies by way of contract negotiation and renewal. TAP management will also review Epsilon procedures as needed for suitability, and instruct Epsilon to revise if necessary.

ACTION PLAN

TAP Pharmaceuticals

Ref. Document: Compliance Assurance Audit

Report Date: 5/28/93

<u>Observation Number</u>	<u>Description</u>	<u>Responsible Individual</u>	<u>Target Date</u>
6.	<p>Epsilon reviews all sampling cards received from sales representatives for the requirements of PDMA documentation. As part of this audit, approximately 11,100 sample cards were examined, and the following noted:</p> <p>a. One card on which Ogen and Omniflox were sampled had been incorrectly signed by a practitioner in San Pedro, California while the pre-printed card identified another practitioner from Lomita, California.</p> <p>b. A nurse practitioner who signed her name with her title of CNP (Certified Nurse Practitioner) was incorrectly sampled Ogen and Omniflox. Neither TAP nor Epsilon procedures allow drug samples to be given to nurse practitioners.</p>	B. Berman	Complete

Action Plan:

TAP Sales Administration Management stressed the importance of detailed sample card review to the vendor in November, 1992. Management will again emphasize the importance of verifying sample receipt documents for all elements of PDMA compliance.

TAP00063280

ACTION PLAN

TAP Pharmaceuticals

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<u>Observation Number</u>	<u>Description</u>	<u>Responsible Individual</u>	<u>Target Date</u>
7.	<p>Sampling documentation for several territories were reviewed and the following noted:</p> <ul style="list-style-type: none"><li>a. An adjustment based on a claim by the sales representative that the physical inventory had been miscounted was posted to Territory CXC06 in violation of Epsilon procedures. Out-of-variances were noted in July and August 1992 as a result of this error.</li><li>b. Many cards were observed to have had changes made in non-PDMA required fields, reportedly by Epsilon clerks. The changes were not signed nor dated, and in some cases included the use of which correction fluid which obscured the original information.</li><li>c. Two physical inventories were submitted for July's ending balance in Territory CXC06. The hard-copy of the original inventory was not in the Epsilon file and its entry into the Epsilon computer system was incorrectly deleted.</li><li>d. Between 2,400 and 2,700 tablets of Ogen 1.25 (18x6x25) were unaccounted for in territory CXB08 from May through October 2, 1992. TAP standard operating procedures require various levels of action to be taken if variances greater than five (5) units have been unreconciled after two (2) months without satisfactory response from the sales representative. As of October 2 the variance has not been reconciled.</li></ul>		

TAP00063281

ACTION PLAN

TAP Pharmaceuticals

Ref. Document: Compliance Assurance Audit

Report Date: 5/28/93

<u>Observation Number</u>	<u>Description</u>	<u>Responsible Individual</u>	<u>Target Date</u>
7.(con't) Action Plan:	a. Epsilon has been instructed to carefully follow procedures. The representative did indeed have a variance due to a miscount of his/her physical inventory, thereby verifying system input/output as accurate in identifying the variance.	B. Berman	Complete
	b. Epsilon has been told to follow compliant documentation practices regarding sample receipt cards. TAP will again emphasize this point.	B. Berman	Complete
	c. The sampling vendor has implemented a revised procedure to now maintain all inventory reports for audit trail verification.	B. Berman	Complete
	d. TAP sampling SOPs have been re-reviewed and re-iterated to in-house sample accountability personnel responsible for performing those procedures. Additionally, the Ogen 1.25mg variance cited was due to an incorrect count by the Representative and has been reconciled.	B. Berman, K. Lowe	Complete

TAP00063282

ACTION PLAN

TAP Pharmaceuticals

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Report Date: 5/28/93

<u>Observation Number</u>	<u>Description</u>	<u>Responsible Individual</u>	<u>Target Date</u>
8.	Currently, Federal Express provides confirmation to TAP of shipments made to practitioners via electronic "acknowledgment of delivery" signatures on an audit basis. Approximately a year ago, Federal Express confirmed nearly 100% of all shipments by providing a copy of actual signatures; however, given the volume of sampling activity and Federal Express' demonstrated accuracy, a program of auditing ten (10) Federal Express shipments each month was instituted. The program requires that Federal Express provide the actual acknowledgment of delivery signatures for ten (10) random shipments. In reviewing Federal Express' performance since June 1992, it was noted that actual signatures could only be provided for 90% of TAP's request. The TAP procedure does not require that the program revert to 100% confirmation by Federal Express no that any other corrective action by initiated by TAP.	B. Berman	Complete

Action Plan: TAP's SOP regarding mail order samples has been modified to include additional requests for AOD verification from Federal Express if 100% confirmation is not achieved from the first sample size.

TAP00063283

ACTION PLAN

TAP Pharmaceuticals

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Report Date: 5/28/93

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9.      **There was no TAP policy or procedure which described the conditions under which returned drug product samples may be restocked.**

Action Plan:      TAP Lupron products are restocked to inventory only with accompanying documentation identifying reason for return and attesting the drug has been maintained in proper storage conditions. Damaged, expired, or product returned without all documentation requirements is destroyed. PPD Returned Goods (D-504) maintains and executes this policy for TAP products.

J. Peterson,      6/1/93  
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Prepared by: R. B. [Signature]      Kevin [Signature]      Date: 5/28/93

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TAP00063284